

## REMARKS

Claims 22-41 are pending in the application.

By the foregoing Amendment, claim 40 is amended to eliminate redundancies in the recitation of the radiation-directing means and the radiation-detecting means.

These changes are believed not to introduce new matter, and entry of the Amendment is respectfully requested.

Based on the above Amendment and the following Remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections, and withdraw them.

### Allowable Subject Matter

Applicant thanks the Examiner for his indication that claim 23 would be allowable if rewritten in independent form. Claim 23 is not being amended at this time, in view of applicant's position that independent claim 22 is patentable over the prior art.

### Objections to the Claims

In paragraph 1 of the Office Action, claim 40 was objected to due to a lack of antecedent basis for "the tissue's homogeneity" and "the linearity of the distance differentiation." This objection is respectfully traversed.

MPEP § 2173.05(e) states in pertinent part:

If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) ("controlled stream of fluid" provided reasonable antecedent basis for "the controlled fluid"). ***Inherent components of elements recited have***

***antecedent basis in the recitation of the components themselves.*** For example, the limitation “the outer surface of said sphere” would not require an antecedent recitation that the sphere has an outer surface. [Emphasis added.]

It is respectfully submitted that homogeneity is an inherent characteristic of the tissue and linearity is an inherent characteristic of the distance differentiation; and that pursuant to MPEP § 2173.05(e), the homogeneity of the tissue and the linearity of the distance differentiation have antecedent basis in the recitation of the tissue and the distance differentiation, respectively.

#### Rejections under 35 U.S.C. § 103

In paragraph 3 of the Office Action, claims 22, 24, 28-31, 33, and 36 were rejected under section 103(a) as being unpatentable over U.S. Patent No. 5,372,136 to Steuer et al. (“Steuer ‘136”) in view of Goodman and Hewlett-Packard. This rejection is respectfully traversed as being based on references that do not teach or suggest the claimed invention.

As recited in independent claims 22, 33, 36, and 41, the present invention detects radiation attenuated by specific components of the blood, transduce energy from the pulse driven and changing blood volume, and integrate these independent constructs into a synergist expression describing a single biologic constituent.

Claim 22 recites “radiation-directing means for directing radiation into the flowing blood within the blood conduit, the radiation-directing means being situated within the blood conduit receiver, the radiation defining a directed radiation comprising a first quantity of radiation at a chosen radiation wavelength that, when directed into the flowing blood within the blood conduit, has: (A) a first attenuation value that varies with the desired biologic constituent concentration in

the flowing blood and (B) a second attenuation value that varies with the concentration of components other than the desired biologic constituent in the flowing blood, which second attenuation value is at least ten times smaller than the first attenuation value.” Similar limitations are also recited in independent claims 33 and 36.

Steuer ‘136 teaches a complex combination of multiple wavelengths to determine biologic constituents such as hematocrit. The method of Steuer ‘136 relies solely on the detection of optical radiation. Steuer ‘136 discloses means for directing radiation into the flowing blood within the blood conduit, the radiation-directing means being situated within the blood conduit receiver, the radiation defining a directed radiation comprising a first quantity of a radiation at a first radiation wavelength which, when directed into the flowing blood in the blood conduit, (A) has a first extinguishment value which varies with the hematocrit in the flowing blood and (B) has a second extinguishment value which varies with the plasma in the flowing blood, which second extinguishment value is at least ten times smaller than said first extinguishment value.

While the method of Steuer ‘136 is augmented by the pulsatile change in intensity brought about by pulsatile changes in the blood volume, Steuer ‘136 does not measure or reference either the change in or the energy of the pulsatile (blood volume) waveform.

The Office Action equates the first and second attenuation values recited in claims 22, 33, and 36 with the first and second extinguishment values taught by Steuer ‘136. However, attenuation value and extinguishment value (also sometimes referred to as extinction value) are not the same. They are mathematically distinct entities. Extinguishment value, represented by the symbol  $\epsilon$ , is

dependent on concentration, as shown by equation (1a) of Steuer '136.<sup>1</sup> In contrast, attenuation value, represented by the symbol  $\alpha$ , is not dependent on concentration, as shown by equation (10) of the present application.<sup>2</sup>

It is conceded in the Office Action that Steuer '136 "does not teach the use of an energy transducer." In its entirety, the "energy-detecting means" recited in claims 22, 33, and 36 reads: "energy-detecting means for detecting energy from the flowing blood within the blood conduit and for measuring the time rate of change of blood volume, the energy-detecting means being situated within the blood conduit receiver, the energy defining a transduced energy comprising a quantity of energy which when detected from the flowing blood within the blood conduit, has a value that varies with the normalized change of the pulsatile blood."

The Office Action characterizes Goodman as supplying the teaching of an energy transducer. It is respectfully submitted that Goodman does not teach or suggest the energy-detecting means recited in claims 22, 33, and 36.

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<sup>1</sup> Equation (1a) of Steuer '136 reads:

$$\ln (I / I_0) = -\epsilon Xd ,$$

where  $I_0$  is the incident intensity of the source radiation,  $I$  is the transmitted intensity of the source through the sample,  $\epsilon$  is the extinction coefficient of the sought for component,  $X$  is the concentration of the sample component in the tissue itself, and  $d$  is the optical path length (distance). Isolating  $\epsilon$ , equation (1a) becomes:

$$\epsilon = - ( \ln (I / I_0) ) / Xd$$

<sup>2</sup> Equation (10) of the present application reads:

$$\alpha = \partial [\ln (i)] / \partial d ,$$

where  $\alpha$  is the bulk attenuation coefficient of the tissue sample,  $i$  is the light flux, or intensity, and  $d$  is the distance.

Goodman does not transduce energy or integrate pulsatile and optical information. He does not use blood volume information.

Goodman synchronizes his optical measure of pulsatile blood oxygen values using an EKG signal to define the optimal time base or window of measurement. He does not process or incorporate pulse information into his application; nor does he utilize pulsatile information other than pulse-related markings on a time line in his oxygen saturation ( $\text{PsO}_2$ ) determination. As in all pulse oximetry devices, Goodman relies on the pulsatile pressure wave to maintain blood volume changes within the physiology of the patient, but quantification of blood volume or pulsatile energy is not part of his science.

Finally, claims 22, 33, and 36 recite “operating means for operating exclusively on the second quantity of the radiation and the transduced energy to determine the desired biologic constituent concentration.” The Office states with respect to this limitation: “The combination teaches operating means (Fig. 1 of Steuer).” However, as discussed above, none of the references teaches or suggests the use of transduced energy, and neither Goodman nor Hewlett-Packard teaches or suggests determining a desired biologic constituent concentration.

The Office Action on page 3 erroneously states: “Hewlett-Packard teaches that this type of coupling of the devices [an EKG, a pulse oximeter, and a blood pressure monitor] is far simpler than many different connections at different points in the body.” Although Hewlett-Packard does teach a rather obvious combination of technologies, contrary to the characterization in the Office Action, the coupling described by Hewlett-Packard is not integration. It is merely co-location for ergonomic purposes, the incorporation of different technologies in proximity. Hewlett-Packard does not suggest

the problem inherent in the serial measure of competing independent parameters, much less the solution to this problem. The technologies disclosed by Hewlett-Packard for the serial measure of competing independent parameters do not share information or facilitate either synergistic or independent measurement. While Hewlett-Packard transduces pressure, Hewlett-Packard does not convert this information into an expression correlative to blood volume, or oxygen saturation, or pulse rate, or energy. Neither does Hewlett-Packard suggest simultaneous integration of the optical, pressure, or electrical signals to yield a correlated whole beyond the scope of each variable. That is, optical and pressure signals do not add up or relate to another constituent. Hewlett-Packard does not integrate information, requires independent serial operation, and does not consider blood volume or changes thereto.

Consequently, the combination of references cannot teach or suggest “operating means for operating exclusively on the second quantity of the radiation and the transduced energy to determine the desired biologic constituent concentration,” as recited in claims 22, 33, and 36.

In view of the foregoing, it is respectfully submitted that the invention as recited in claims 22, 24, 28-31, 33, and 36 is patentable over the combination of Steuer ‘136, Goodman, and Hewlett-Packard, and that the rejection should be withdrawn.

## Double Patenting Rejections

### 1. Rejection based on Steuer '958

In paragraph 5 of the Office Action, claims 22 and 24-41 were rejected under the doctrine of obviousness-type double patenting based on U.S. Patent No. 6,181,958 to Steuer et al. ("Steuer '958"). This rejection is overcome by a terminal disclaimer submitted herewith.

### 2. Rejection based on Steuer '627

In paragraph 6 of the Office Action, claims 22, 24, 28, 33, and 36 were rejected under the doctrine of obviousness-type double patenting based on U.S. Patent No. 5,499,627 to Steuer et al. ("Steuer '627") in view of Goodman and Hewlett-Packard. This rejection is respectfully traversed, for substantially the same reasons as set forth above with respect to the rejection of claims 22, 24, 28-31, 33, and 36 under 35 U.S.C. § 103(a) based on Steuer '136, Goodman, and Hewlett-Packard.

It is noted that the application that matured into Steuer '627 was a divisional of the application that matured into Steuer '136, and the disclosures of Steuer '627 and Steuer '136 are therefore substantially identical. The first and second extinguishment values recited by the claims of Steuer '627 are mathematically distinct from the first and second attenuation values recited by claims 22, 33, and 36 of the present application. Neither Steuer '627 nor Goodman teaches or suggests the energy-detecting means that is missing from the claims of Steuer '627. Finally, the calculation means recited in the claims of Steuer '627 does not "determine the desired biologic constituent concentration"; and Steuer '627 does not teach or suggest the determination of a desired biologic constituent concentration.

In view of the foregoing, it is respectfully submitted that the invention as recited in claims 22, 24, 28, 33, and 36 is patentable over the claims of Steuer '627 in combination with Goodman and Hewlett-Packard, and that the rejection should be withdrawn.

Conclusion

All objections and rejections have been complied with, properly traversed, or rendered moot. Thus, it now appears that the application is in condition for allowance. Should any questions arise, the Examiner is invited to call the undersigned representative so that this case may receive an early Notice of Allowance.

Favorable consideration and allowance are earnestly solicited.

Respectfully submitted,

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